

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK

-----	X	
ONY, Inc.,	:	
	:	
Plaintiff,	:	Case No. 11-cv-1027-WMS
	:	
-against-	:	
	:	<b>ORAL ARGUMENT REQUESTED</b>
Cornerstone Therapeutics, Inc., et al.,	:	
	:	
Defendants.	:	
-----	X	

**REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF  
DEFENDANT PREMIER, INC.'S MOTION TO DISMISS FOR FAILURE  
TO STATE A CLAIM**

McDERMOTT WILL & EMERY LLP  
Lauren E. Handel  
340 Madison Avenue  
New York, New York 10173-1922  
212-547-5400  
lhandel@mwe.com

*Attorneys for Defendants Premier, Inc. and Frank R. Ernst*

Nothing in Plaintiff ONY, Inc.'s Opposition papers saves its injurious falsehood claim against Premier, Inc. and Frank Ernst<sup>1</sup>.

**I. THE ALLEGEDLY "FALSE" STATEMENTS ONY NOW SINGLES OUT ARE NON-ACTIONABLE EXPRESSIONS OF SCIENTIFIC OPINION.**

In opposition to Defendants' motions to dismiss for failure to state a claim, Plaintiff attempts to characterize scientific opinions expressed in the Article as "false" statements of fact. As Plaintiff recognizes, only statements of fact, not opinion, are capable of being false and therefore actionable. *Brian v. Richardson*, 87 N.Y.2d 46, 51 (1995). ONY identifies six specific sentences in the Article, all stating essentially that, in the authors' study, patients treated with ONY's product, Infasurf (calfactant), were found to have a higher mortality rate than patients treated with Chiesi's product, Curosurf (poractant alfa).<sup>2</sup> (Pl's Mem. in Opp. to Defs Nature America and Lawson (Doc. 65) at 5). This argument suffers from two fatal flaws. First, when read in context (as they must be), the statements ONY identifies are reasonably understood as

---

<sup>1</sup> Defendant Frank Ernst joins in this Reply Memorandum in the event that his Motion to Dismiss for Lack of Personal Jurisdiction is denied.

<sup>2</sup> In its Opposition briefs, ONY identifies the following quotes from the Article as the false statements of fact on which its injurious falsehood claim ostensibly is based:

- "Result: Calfactant was associated with a 49.6% greater likelihood of death than poractant alfa." (Balin Decl. (Doc. 30) Exh. A at 1)
- "Conclusion: Poractant alfa treatment for RDS was associated with a significantly reduced likelihood of death when compared with calfactant." (*Id.* at 1)
- "Calfactant was found to be associated with a 49.6% greater likelihood of death than poractant alfa." (*Id.* at 4)
- "This model found calfactant to be associated with a significantly greater likelihood of death than poractant alfa." (*Id.* at 5)
- This study "show[ed] a significant greater likelihood of death with calfactant than poractant alfa." (*Id.* at 5)
- "[T]his large retrospective study of preterm infants with RDS found lower mortality among infants who receive poractant alfa, compared with infants who received either calfactant or beractant, even after adjusting for patient characteristics such as gestational age and BW, and after accounting for hospital characteristics and center effects." (*Id.* at 6)

expressions of scientific opinion, not fact. Second, the facts asserted in these statements – *i.e.*, the reported study results – are not what ONY alleges in its Complaint to be false.

**A. Viewed In Context, The Statements ONY Now Identifies As “False” Are Opinions Reflecting The Authors’ Scientific Interpretation Of Data.**

By taking certain sentences in the Article out of context, ONY attempts to create the impression that it is challenging false expressions of fact, rather than opinion. For example, ONY points to the statement “[c]alfactant was associated with a 49.6% greater likelihood of death than poractant alfa” as a purportedly actionable false statement of fact. This statement, and the other five identified in ONY’s opposition as allegedly “false” statements of fact, must be read in the overall context of the Article. *See Mann v. Abel*, 10 N.Y.3d 271, 276 (2008) (court must consider “whether either the full context of the communication in which the statement appears or the broader social context and surrounding circumstances are such as to signal . . . readers or listeners that what is being read or heard is likely to be opinion, not fact”).

Any reasonable reader of the Article would understand that, in context, the authors of these statements were not reporting some abstract, categorical truths, but rather the results of a study that relied upon specific data and statistical analysis techniques that the authors selected based on their scientific expertise. The data on which the study was based and its statistical methods are described in detail in the Article. (*See* Balin Decl. (Doc. 30) Exh. A at 2-4.) It is evident to even non-technical readers – and certainly to the sophisticated, intended audience of the Article – that this study was not a simple head-count of infants who died while being treated with Infasurf versus Curosurf, but rather involved a complex study design. (*See, e.g., id.* at 2 (“The comparison between surfactants in terms of mortality was based on a mixed multilevel, multivariable logistic regression model.”); *id.* (“To assess the sensitivity of the results, three alternative models were estimated.”).) Given the complexity of the study, the authors’

statements of their findings and conclusions necessarily express their scientific interpretation (*i.e.*, opinion) of the data they selected and analyzed.

**B. ONY's Complaint Does Not Allege That The Authors Falsely Reported The Results Of Their Study.**

To the extent that the six statements ONY now singles out as “false” are factual in nature, they are not the purported falsehood ONY actually challenges in its Complaint. Tellingly, the Complaint does not quote any of the six statements. Nor does it incorporate the text of Article by reference. That is because ONY's Complaint does not allege that the authors falsely reported the findings of their study. Rather, ONY's claim is that the authors' findings are unreliable because they should have considered additional data – namely, the patients' length of stay. (Compl. ¶¶ 35, 37, 67.)

An example illustrates the point. The statement “[c]alfactant was associated with a 49.6% greater likelihood of death than poractant alfa” is factual in that it reports a finding of the authors' study. This statement is capable of being proven true or false because the study could be audited to determine whether the authors accurately reported their results. Alternatively, a qualified person with access to the same data could replicate the authors' study and see if they get the same results. But the factual aspects of this statement – *i.e.*, its reporting of study results – is not really what ONY complains about. Nowhere in ONY's Complaint or Opposition Memoranda does it claim that the authors falsely reported their findings. Rather, ONY alleges that the authors' findings and conclusions are “false” because they are scientifically unreliable, given that the authors did not consider data on the patients' length of stay. (Compl. ¶ 67.) The essence of ONY's gripe is that the study was “subject to selective distortion,” length of stay data was necessary to examine the similarity of the subject patients, and that the authors intentionally omitted the length of stay data “to postulate, promote and disseminate false conclusions . . . .”



(Compl. ¶ 37.) Thus, ONY's real complaint is with the study design or interpretation of results, which are non-actionable matters of scientific opinion, not the authors' factual reporting of their study results.

## II. ONY HAS NOT JUSTIFIED ITS FAILURE TO PLEAD SPECIAL DAMAGES.

ONY wrongly argues that it has satisfied the requirement to plead special damages by alleging a "diminution in the inherent value of its business in the amount of 10% to date (including in the amount of \$7.6 million as measured by two times EBIDTA)." Putting aside that this is the very type of round-number, non-itemized loss that is insufficient to state special damages under New York law, *Drug Research Corporation v. Curtis Publishing Company*, 7 N.Y.2d 435, 437 (1960), Plaintiff also has failed to allege facts establishing that any part of this claimed loss of earnings is "the natural and immediate consequence of the disparaging statements" made by Premier or Ernst. *Kirby v. Wildenstein*, 784 F. Supp. 1112, 1116 (S.D.N.Y. 1992). The only plausible link between Premier and Ernst's participation in the publication of the Article and ONY's alleged loss of earnings would be a loss of sales to customers who had read the Article and decided not to buy ONY's product. Yet, ONY has identified no such customers or itemized the value of their lost sales. Furthermore, ONY cannot avoid the requirement to specifically identify lost customers by characterizing its damages as a loss in earnings. See *Edward B. Beharry & Co., Ltd. v. Bedessee Imps., Inc.*, No. 09-CV-0077, 2010 U.S. Dist. LEXIS 27404, \*29 (E.D.N.Y. March 23, 2010).

Although, in one case, the Southern District of New York allowed a narrow exception to the requirement that plaintiffs identify lost customers, courts have declined to apply this exception in other cases. See *Verizon Directories Corp. v. Yellow Book USA, Inc.*, 309 F. Supp. 2d 401, 406 (E.D.N.Y. 2004); *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 75 F. Supp. 2d 235, 240 (S.D.N.Y. 1999); *Kirby*, 784 F. Supp. at 1116. In *Charles Atlas, Ltd. v. Time-*

*Life Books, Inc.*, 570 F. Supp. 150 (S.D.N.Y. 1983), the court found it was unnecessary for the plaintiff to identify its lost customers because its product was sold only by mail order and the defamatory statement was disseminated so widely that it was “virtually impossible to identify those who did not order the plaintiff’s product because of the article.” *Id.* at 156. In that case, the plaintiff had alleged specific monetary damages, down to the dollar, of sales losses and its special advertising expenditures to counteract the alleged disparagement. *Id.* at 155. Here, in contrast, ONY has not pleaded specific monetary damages of lost sales down to the dollar. Moreover, it has shown that it has direct communication with its customers – which, presumably, consist of a finite number of medical institutions – through ONY’s Account Sales Representatives. (See 2/6/2012 Decl. of E. Egan (Doc. 68); 2/9/2012 Supp. Decl. of E. Egan (Doc. 70).) Unlike the plaintiff in *Charles Atlas*, it would not be “virtually impossible” for ONY to determine which of its customers it may have lost and to find out if those customers’ decisions were prompted by the Article. Thus, there is no reason to excuse ONY from the requirement that it identify lost customers with specificity.

### **CONCLUSION**

For all of the foregoing reasons and for the reasons stated in the Memorandum of Law in Support of Premier Inc.’s Motion to Dismiss for Failure to State a Claim, ONY’s Fifth Claim for Relief should be dismissed with prejudice.

Dated:

New York, New York.  
February 13, 2012

Respectfully submitted,

McDermott Will & Emery LLP  
340 Madison Avenue  
New York, New York 10173-1922  
212 547 5400  
lhandel@mwe.com

By: s/Lauren E. Handel

Lauren E. Handel  
*Attorneys for Defendants*  
*Premier, Inc. and Frank Ernst*